Actuarial follow-up event rates:

Events	6-months	12-months	24-months
- Death (%)	5	8	14
- MI (%)	7	8	8
- CABG (%)	7	9	12
- PTCA (%)	6	8	12
- Event-free survival (%)	75	67	55

Event-free survival = freedom from death, MI, CABG or PTCA

Conclusion: Similar to PTCA in SVG lesions and in contrast to stents in native coronaries, patients with stents in SVG's exhibit a disappointing attrition in late clinical outcomes beyond one year. Both increasing mortality and repeat revascularization procedures contribute to the 2-year 55% event-free survival. We surmise that further deterioration at the stent site (i.e. "late" restenosis), increasing non-TLR events, and less favorable baseline characteristics are responsible for these findings.

3:15

710-6 Economic Impact of Reduced Anticoagulation After Saphenous Vein Graft Stent Placement

S. Chiu Wong, Jeffrey J. Popma, Ya Chien Chuang, Gary S. Mintz, Lowell F. Satler, Kenneth M. Kent, Augusto D. Pichard, Mun K. Hong, Theresa A. Bucher, Kathi Donovan, Kathy Morgan, Alan Merritt, David Kaufman, Martin B. Leon. *Washington Hospital Center, Washington, DC*

Stent (S) placement in the treatment of saphenous vein graft (SVG) lesions has been limited by increased bleeding complications and prolonged hospital stay due to intense anticoagulation after procedure. Intravascular ultrasound (IVUS) guided S implantation with Reduced Anticoagulation (no heparin or coumadin post procedure) VEin graft Stent trial (RAVES) was designed to address these issues. To assess the economic impact of this novel S placement technique, we compared the in-hospital complications and costs in 33 RAVES pts with 77 pts who underwent standard (Non-RAVES) S deployment for SVG lesions. Enrollment criteria, pt demographics and pre-treatment angiographic findings were similar between the 2 groups. Vascular/bleeding complications = hematoma with >15% drop in hematocrit, A-V fistula, pseudoaneurysm, retroperitoneal bleed, and gastrointestinal bleed.

	RAVES	Non-RAVES	P value
Vascular/bleeding complications (%)	3.1	19.1	0.04
Transfusion/Surgical repair (%)	0/0	24.0/9.3	0.002/0.1
Subacute thrombosis (%)	0	1.3	1.0
In-hospital Complications (%):	0/0/0/0	1.3/0/0/1.3	1.0/-/-/1.0
Death/MI/CABG/Repeat PTCA			
Length of stay (days)	4.3 ± 2.0	8.2 ± 4.9	<0.0001
Costs ($)	8,734 ± 2,238	14,182 ± 6,938	<0.0001

There were no out-of-hospital ischemic complications reported up to 1 month (vulnerable period for subacute thrombosis) after procedure in both groups.

In Conclusion: IVUS guided S implantation with reduced anticoagulation resulted in marked reduction in bleeding events and no increase in procedural or 30-day complications. The hospital length of stay was significantly reduced in the RAVES pts with substantial cost saving (38.4%) compared with Non-RAVES pts. If this observation holds true in a larger cohort, S placement with reduced anticoagulation should be the treatment of choice for SVG lesions.

711 Adjunctive Therapy and Outcome With PTCA

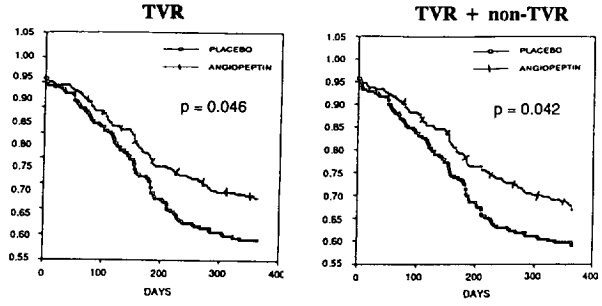
Monday, March 20, 1995, 2:00 p.m.–3:30 p.m.
Ernest N. Morial Convention Center, Room 102

2:00

711-1 Angiopeptin Significantly Improves Twelve Months Event Free Survival Following PTCA in a Randomized Double Blind Study

Håkan Emanuelsson, Kevin J. Beatt, Jens-Peder Bagger, Raphael Balcon, Juhani Heikkila, Jan Piessens, Marc Schaeffer, Harry Suryapranata, Marie L. Foegh, European Angiopeptin Study Group. *Henri Beaufour Institute, Washington, D.C.*

Patients (n = 553) undergoing coronary balloon angioplasty in 18 European centers were randomized to receive a five-day continuous s.c. infusion of either placebo or Angiopeptin (6 mg/day) beginning the day prior to PTCA. The inclusion criteria were broad and only patients with a Q-wave infarction within the last 4 weeks prior to PTCA were excluded. The primary endpoint for 12 months outcome was the composite of death, non-fatal MI or repeat revascularization (PTCA or CABG). Revascularization data were collected on both the original target vessel and non-target vessels. The event free survival curve for all patients shows Angiopeptin to significantly (p = 0.046) decrease the clinical events compared to placebo. If non-target vessels are included the improved event free survival is maintained (p = 0.042). This significant decrease in clinical event rate was already obtained at 6 months (p = 0.034, odds ratio = 0.66, 95% confidence interval 0.45–0.97).



This significant effect of Angiopeptin in decreasing clinical events in patients undergoing PTCA is maintained at one year.

2:15

711-2 Recombinant-hirudin (CGP 39 393) Reduces the Incidence of Major Adverse Cardiac Events, Reported within the First 96 Hours Post-Angioplasty in Unstable Patients (Braunwald Classification) Pre-treated by Heparin

Patrick W. Serruys, Keith A.A. Fox, Jean-Paul R. Herrman, Doris Bach [1], Philip Close [1], Jaap W. Deckers, HELVETICA investigators. *Thoraxcentrum, Erasmus University, Rotterdam, The Netherlands;* [1] *Ciba-Geigy Ltd, Basle, Switzerland*

Background: r-Hirudin (Hir), an antithrombin may prevent thrombosis post angioplasty thereby reducing early thrombotic events and late restenosis.

Methods: 1141 patients were prospectively randomized to 1) 10,000IU heparin bolus + 15 IU/kg/hr iv heparin 24 hrs + sc placebo (HEP), or 2) Hir 40 mg bolus + 0.2 mg/kg/hr Hir iv 24 hrs + sc placebo (HIR i.v.), or 3) Hir 40 mg bolus + 0.2 mg/kg/hr Hir iv 24 hrs + 40 mg Hir sc bid for 3 days (HIR i.v. + s.c). All patients had unstable angina pectoris. Study treatment started just prior to angioplasty.

Secondary endpoint: incidence of early (≤96 hrs) major adverse cardiac events. Randomization was stratified for presence or absence of heparin pretreatment ("ON" vs. "OFF" heparin):

Results	HEP		HIR i.v.		HIR i.v. + s.c.	
	"ON"	"OFF"	"ON"	"OFF"	"ON"	"OFF"
N=	115	267	110	271	110	269
Any Event %	17.4	8.2	6.4	8.5	6.4	5.2
Death %	0.9	0.4	–	–	–	–
MI %	7.0	2.2	2.7	3.7	4.6	1.5
CABG %	7.0	4.5	3.6	3.7	1.8	2.2
Re-PTCA %	2.6	1.1	–	1.1	–	1.5

Conclusion: In patients with unstable angina who were receiving heparin at the time of randomization, hirudin i.v. for 24 hours, with or without hirudin s.c. for 72 hrs, substantially reduces the incidence of major adverse cardiac events encountered during the first 96 hrs following PTCA, when compared to heparin as anticoagulant (–63%, 6.4% vs 17.4%, Chi square p = 0.007). This favourable effect is obtained without a significant increase in major bleeding complications (HEP 6.2%, HIR i.v. 5.5%, HIR i.v. + s.c. 7.6%).

2:30

711-3 A Multicenter, Randomized, Double-Blind Pilot Trial of Standard Versus Low Dose Weight-Adjusted Heparin in Patients Treated with the Platelet GP IIb/IIIa Receptor Antibody c7E3 During Percutaneous Coronary Revascularization

A. Michael Lincoff, James E. Tcheng, Theodore A. Bass, Jeffrey J. Popma, Paul S. Teirstein, Neal S. Kleiman, Harlan F. Weisman, Maura H. Musco, Catherine F. Cabot, Lisa G. Berdan, Robert M. Califf, Eric J. Topol, PROLOG Investigators. *Cleveland Clinic Foundation, Cleveland, OH; Duke University, Durham, NC*

Blockade of the platelet GP IIb/IIIa receptor by the monoclonal antibody c7E3 during high-risk coronary intervention reduced the 30-day endpoint of death, MI, or urgent revascularization by 35% in the EPIC trial, but was accompanied by an increase in the rate of major bleeding. In EPIC, heparin was ad-

MONDAY PM